REMARKS

Docket No.: 025444.1059-US02

Claims 1-41 have previously been cancelled, without prejudice to or disclaimer of the subject matter recited therein. Claims 85, 86, 87, 88, 91 and 92 have additionally been cancelled in this Response, also without prejudice to or disclaimer of the subject matter recited therein. Claims 42-84, 89-90, and 93-120 are currently pending, with claims 42, 44, 45, 49, 50, 72, 79, 89, 93, 95, 100, 102, 103, 106 and 108 being independent. Claims 42, 44, 46, 48, 49, 50, 51, 73, 74, 79, 80, 89, 90, 93, 94, 95, 96, 100, 104, 105, 106, 107, 108 and 109 have been amended to more distinctly claim Applicant's invention. Support for these amendments can be found throughout the specification and in the originally filed claims. In particular, claims 50 and 108 have been amended to correct typographical errors in the amounts of microcrystalline cellulose and magnesium stearate recited in those claims, in view of Applicant's disclosure in Example 3 at pages 22-23 of the specification. No new matter has been added by these amendments.

The Office Action of April 5, 2007 sets forth a restriction requirement amongst two groups of claims:

- Claims 42-71, drawn to a solid composition comprising an immediate release layer of desloratedine and a sustained release layer of pseudoephedrine, classified in class 424, subclass 472; and
- II. Claims 72-120, drawn to a solid composition comprising desloratedine, classified in class 424, subclass 465.

The Office Action also imposes an election of species requirement. If Applicant chooses to elect Group I claims (i.e., claims 42-71), then the following further election of species is required amongst the following methods of treatment:

- (a) Method of treating allergic or inflammatory conditions of upper/lower airway passages;
 - (b) Method of treating the signs and symptoms of nasal congestion;
 - (c) Method of treating the signs and symptoms of urticaria; and

Docket No.: 025444.1059-US02

(d) Method of treating nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis.

If Applicant chooses to elect Group II claims (i.e., claims 72-120), then the following further election of species is required amongst the following method of treatment:

- (a) Method of treating allergic or inflammatory conditions of upper/lower airway passages;
 - (b) Method of treating the signs and symptoms of urticaria; and
- (c) Method of treating nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis.

Applicant elects, with traverse, to proceed with the claims of Group II, claims 72-120.

Furthermore, with respect to the method of treatment claims recited in Group II, Applicant elects, with traverse, to proceed with those method claims directed to species (c), namely, a method of treating nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis. Method claims amongst the Group II claims that are readable on this species include claims 99, 116, 118, 119 and 120. Applicant submits that the composition claims in Group II (i.e, claims 72-84, 89-90, 93-96, 100-101 and 103-109) are not limited by any method of treatment. Consequently, each of these composition claims is entitled to full consideration by the Office in this application.

The Office Action contends that the inventions of Groups I and II should be examined separately. However, in reasons provided to support this contention, the Office Action mischaracterizes Applicant's claimed invention, as discussed below.

First, the Office Action suggests that the claims placed in Group I uniformly require (1) an immediate release layer of desloratedine and two pharmaceutically acceptable antioxidants; (2) a sustained release layer of pseudoephedrine; and (3) a sustained release agent, wherein the total amount of desloratedine degradation products in the solid composition is less than or equal to about 2% by weight. However, this characterization is not correct for all claims in Group I. For example, independent claims 44 and 45 do not recite "two pharmaceutically acceptable antioxidants."

Second, the Office Action suggests that, in contrast to Group I claims, Group II claims

Docket No.: 025444.1059-US02

contemplate "a <u>single</u>-layered, <u>non</u>-sustained or non-controlled release formulation that requires only <u>one</u> active agent -- desloratadine and does not require pseudoephedrine" (emphasis in original). However, this is an inappropriate characterization of the claims in Group II. None of the independent claims in Group II specifically requires the claimed invention to be a single-layered, non-sustained or non-controlled release formulation. Each of independent claims 72, 79, 89, 93, 95, 100, 103, 106 and 108 is directed to a solid composition having various recited features, which, given the "comprising" transition phrase, might conceivably read on solid compositions that have one or more layers and that are formulated as an immediate or a sustained or controlled release formulation.

In view of the above mischaracterizations of the claimed invention, Applicant submits that the restriction requirement is inappropriate and should be withdrawn.

Furthermore, Applicant notes that the inventions of Groups I and II in the restriction requirement as well as the various species of method claims subject to the election of species requirement are sufficiently closely related that a proper search of any of the claims would, of necessity, require a search of the others. Thus, it is submitted that all of the claims can be searched together, and that a duplicative search, with possibly inconsistent results, may occur if the restriction requirement is maintained. Also, it is submitted that any nominal burden placed upon the Examiner to search an additional subclass necessary to determine the art relevant to Applicant's overall invention is significantly outweighed by the public interest in not having to obtain and study several separate patents in order to have available all of the issued patent claims covering Applicant's invention.

In view of the above, reconsideration and withdrawal of the restriction and election of species requirements are requested.

Favorable consideration and early examination on the merits are requested. Applicant requests that the Examiner contact Applicant's undersigned representative should there be any

Dated: May 7, 2007

(May 5, 2007 = Saturday)

questions pertaining to this application.

Respectfully submitted,

Natalie M. Derzko

Registration No.: 48,102

Paul J. Berman

Registration No.: 36,744

COVINGTON & BURLING LLP

Docket No.: 025444.1059-US02

1201 Pennsylvania Avenue, N.W. Washington, DC 20004-2401

(202) 662-6000

Attorneys for Applicant